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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/624,467

07/23/2003

Peter Berrang

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EXAMINER

HOPKINS, CHRISTINE D

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

08/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/624,467

Applicant(s)

BERRANG ET AL.

Examiner

Christine D. Hopkins

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,7-9,17-19,21,27-32 and 43-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,7-9,17-19,21,27-32,43,44 and 46-56 is/are rejected.
- 7) ☒ Claim(s) 45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed 14 May 2007. Claims 1-2, 4, 7-9, 17-19, 21, 27-32, and 43-56 are now pending. The Examiner acknowledges the amendments to claims 1-2, 7-9, 17-19, and 27-31, as well as the cancellation of claims 3, 5-6, 10-16, 20, 22-26 and the addition of claims 43-56.

Claim Objections

2. Claim 54 is objected to because of the following informalities: at line 3, "complaint" should apparently read --compliant--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 at line 3 recites the limitation "said pair of electrically conductive bonding layers." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-2, 4, 7, 18-19, 27-28, 44 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Kroll et al. (U.S. Patent No. 6,005,955). Kroll et al. (hereinafter

Kroll) disclose an electromechanical transducer for an implantable hearing aid.

Regarding claim 1, 7 and 54, Kroll teaches a carrier **105**, or “housing” that is hermetically sealed, wherein the sealing has an end comprising a “wall” such that lead lines **85** and **90** enter through feedlines in the “wall,” and the carrier contains a “vibrational assembly” of transducer elements and inertial mass (col. 8, lines 65-67 - col. 9, lines 1-5). The transducer, or “controllable vibrating element” may be composed of a plurality of stacked piezoelectric transducers, or piezoceramic components (col. 1, lines 51-60). The “vibrating element,” or transducer, consists of two piezoelectric elements **100A-B** (col. 8, lines 32-37), of opposite polarity whereby element transducer **100A** will expand longitudinally in response to a received electric signal and consequently, element transducer **100B** will contract longitudinally when a voltage is applied (col. 8, lines 53-61). The piezoelectric layers, stacked according to opposing polarity, may be bonded together (col. 6, lines 7-14) and may be “disk-shaped” or cylindrical (col. 12, lines 46-51).

With reference to claims 2 and 4, Kroll further discloses the device having a microphone, “electronics” for producing electrical signals, and a drive coil (col. 5, lines 36-46). An array of electrodes aids in stimulating the nerve fibers, ultimately transmitting an impulse to the brain that is interpreted as sound (col. 5, lines 5-17).

Regarding claims 18-19 and 28, Kroll teaches a hermetic housing as described with reference to claim 1, having a "top" constructed of titanium (col. 8, lines 65-67), such an element having flexible properties. The "top" may be connected to a stack of piezoelectric crystals such as shown in Fig. 11A. Stacked transducers **140, 145** contain the electrically bonded piezoelectric elements. They are interconnected via lead wires **85, 90** that feed through and connect to, the "flexible top" (col. 10, lines 59-67 - col. 11, lines 1-16), also in accordance with claim 44.

Regarding claim 27, "the base end" of the housing, is connected to a plurality of lead wires **85, 90** (see Fig. 7) where the lead wires are disposed through the housing "base end."

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (U.S. Patent No. 6,005,955) in view of Lesinski et al. (U.S. Patent No. 5,772,575). Kroll discloses the invention as claimed, see rejection supra; however Kroll fails to teach conductive bonding layers extending beyond the outer circumference of the piezoelectric elements. Lesinski et al. (hereinafter Lesinski) teaches a hearing device to be implanted within a subject's ear. Regarding claim 8, Lesinski discloses that

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conductive bonding layers (**45a** in Fig. 3) extends beyond the piezoelectric element, or transducer **45** (col. 11, lines 43-52), thus enabling it to serve as a "contact pad."

Therefore, at the time of the invention, it would have been obvious for one having ordinary skill in the art to have incorporated a conductive layer, as taught by Lesinski, extending beyond a transducer, similar to that disclosed by Kroll, for providing an electrical contact for a particular element such as a lead wire or electrode.

Regarding claim 9, the combination of Kroll and Lesinski discloses the invention as claimed, see rejection supra, however the combination does not expressly disclose that an etched metal clip joins the electrically conductive bonding layers. Instead, Kroll and Lesinski disclose conductive bonding layers (**45a** and **45b**) formed of metallic and cermet layers (col. 11, lines 43-58 of Lesinski). At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to utilize a bent etched metal clip as the electrically conductive link because Applicant has not disclosed that utilizing a bent etched metal clip provides an advantage, is used for a particular purpose, or solves a state problem. One of ordinary skill in the art, furthermore, would have expected Kroll's and Lesinski's metallic/cermet bonding layers to perform equally well with either the layers taught by Kroll and Lesinski or the claimed "etched metal clip that has been bent" because both would perform the same function of electrically connecting the bonding layers. Therefore, it would have been prima facie obvious to modify the invention of Kroll and Lesinski to obtain the invention as specified in claim 9 because such a modification would have been

considered a mere design consideration which fails to patentably distinguish over the prior art of Kroll and Lesinski.

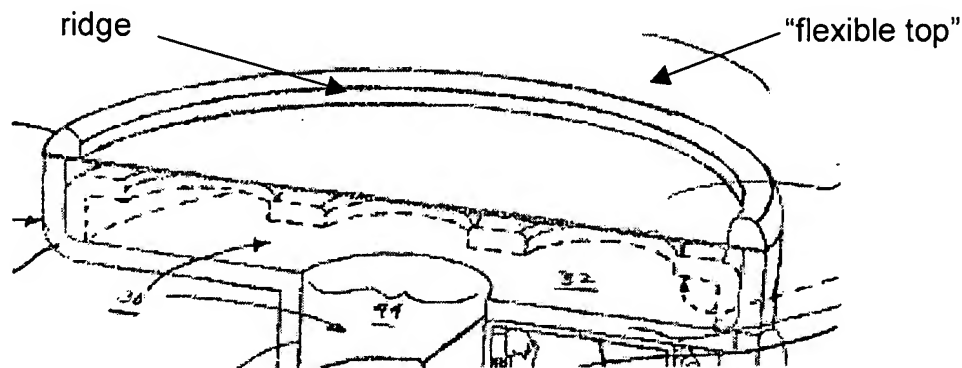
9. Claims 17 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (U.S. Patent No. 6,005,955) in view of Maynard (U.S. Patent No. 6,408,496). Kroll discloses the invention as claimed, see rejection supra; however Kroll fails to teach a particular material used to construct the inertial mass. Maynard teaches the fabrication of a vibrational transducer suited for use in a hearing mechanism. Regarding claim 17, Maynard discloses an inertial mass composed of a dense metal such as gold or platinum (col. 6, lines 4-7). Therefore, at the time of the invention it would have been obvious for one having ordinary skill in the art to have made an inertial mass such as that taught by Kroll of a material such as gold as disclosed by Maynard, for providing a metallic, dense element that will vibrate in response to a vibration received from a transducer within a hearing device.

Regarding claims 31-32, the housing may comprise a biocompatible coating, at least in part of silicon. Therefore, at the time of the invention it would have been obvious for one having ordinary skill in the art to have constructed a housing as taught by Kroll to be coated with a biocompatible material such as that disclosed by Maynard to implant a hearing device into a particular orientation in a human ear and aid compatibility with human tissue.

10. Claims 21 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (U.S. Patent No. 6,005,955) in view of Miller (U.S. Pub. No. 2002/0071585). Kroll discloses the invention as claimed, see rejection supra; however

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Kroll fails to teach a flexible top having one or more ridges in the form of concentric rings impressed into the top. Miller teaches an implantable hearing device having a microphone within a housing. Regarding claims 21 and 29-30, Miller discloses a diaphragm or "flexible top" **52** made of titanium, as in the instant application, and disk-shaped (defining a "concentric ring") with a "ridge" or "groove" (see depiction below), having a thickness of 10 to 20 microns [0029].



Therefore, at the time of the invention it would have been obvious for one having ordinary skill in the art to have constructed a flexible top having the dimensions such as that taught by Miller, into a hearing device similar to that disclosed by Kroll, to provide a flexible basis with a ring arrangement for a hearing device to be implanted into a particular orientation in a human ear and aid osseointegration of the device within the ear.

11. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (U.S. Patent No. 6,005,955). Kroll discloses the invention as claimed, see rejection supra, however Kroll does not expressly disclose that there are between 10 and 100 of

said piezoelectric elements in said stack. Instead, Kroll discloses a plurality of piezoelectric elements resulting in different vibration frequency responses such that an overall frequency response bandwidth of the housing is increased (col. 11, lines 1-7). At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to increase the number of piezoelectric elements in each stack because Applicant has not disclosed that inducing a hearing intensity to the implantee of up to about 120 dB by utilizing 10-100 piezoelectric elements provides an advantage, is used for a particular purpose, or solves a state problem. One of ordinary skill in the art, furthermore, would have expected Kroll's plurality of piezoelectric elements to perform equally well with either the amount taught by Kroll or the claimed 10-100 piezoelectric elements because both would perform the same function of increasing the implantee's response to an increased frequency range. Therefore, it would have been prima facie obvious to modify Kroll to obtain the invention as specified in claim 43 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Kroll.

12. Claims 46-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (U.S. Patent No. 6,005,955) in view of Berrang et al. (U.S. Patent No. 6,516,228). Kroll et al. disclose an implantable hearing device comprising a vibrational assembly enclosed in, and configured to vibrate, a hermetic housing, wherein the hermetic housing comprises a sealed end, wherein the sealed end comprises a wall (col. 8, lines 65-67 - col. 9, lines 1-5); however, Kroll fails to disclose that one or more grooves are formed in the wall. Berrang et al. (hereinafter Berrang) disclose a totally

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implantable microphone for use with an implanted hearing aid. Berrang similarly discloses a housing cylinder, preferably made of titanium, which may also be hermetically encapsulated (col. 8, lines 25-34 and col. 5, lines 35-41). Regarding claims 46-47 and 50-53, Berrang discloses that radially-disposed grooves 20 (Fig. 5), which penetrate to about half of the thickness of the wall, act to osseointegrate the housing to the bony wall of the auditory canal (col. 8, lines 25-28). Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have constructed an implantable auditory device similar to that disclosed by Kroll with grooves constructed in an implantable housing as suggested by Berrang for aiding osseointegration.

Regarding claims 48-49, Berrang does not disclose expressly that the width and depth of the grooves are about 0.05 to 0.2 mm. Instead, Berrang indicates that the overall length of the implantable housing containing the grooves is 3-7 mm, preferably about 5 mm (col. 6, lines 9-11) and a diameter of 3 mm to 5 mm, and preferably about 4 mm (col. 7, lines 63-65).

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to construct the grooves of Berrang to have a width and depth of about 0.05 to 0.2 mm because Applicant has not disclosed that constructing the grooves of such dimensions provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Berrang's implantable auditory device and applicant's invention, to perform equally well with either the dimensions taught by

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Berrang or the claimed 0.05 to 0.2 mm grooves because both dimensions would perform the same function of aiding osseointegration. Therefore, it would have been prima facie obvious to modify Berrang to obtain the invention as specified in claims 48-49 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Berrang.

13. Claims 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (U.S. Patent No. 6,005,955) in view of Money (U.S. Patent No. 5,782,744). Kroll discloses the invention as claimed, see rejection supra; however, Kroll fails to disclose that the hermetic housing is partially coated with silicone. Money teaches an implantable hearing device which senses sounds by monitoring pressure variations in the cochlear fluid. Regarding claims 55 and 56, Money teaches the use of silicone rubber, a biocompatible material which partially coats a microphone **40C**, because of its close mechanical impedance match to cochlear fluid (col. 3, lines 26-40). Kroll similarly teaches an implantable hearing device having a compliant housing, see rejection supra, but does not specify silicone as the compliant material. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have incorporated a compliant material such as silicone as suggested by Money, to an implantable device similar to that as taught by Kroll, in order to increase the impedance to acoustic waves between the microphone housing and the surrounding bone and tissue.

Allowable Subject Matter

14. Claim 45 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: regarding claim 45, the prior art of record does not teach or fairly suggest a hearing device having a base ring attached to a wall of a hermetic housing, a non-conductive insert attached to the base ring, and an interface element attached to at least one electrically conductive bonding layer and the non-conductive insert.

Response to Arguments

15. Applicant's arguments filed 14 May 2007 with respect to the rejection of claims 3 and 22-25 under 35 U.S.C. 101 have been fully considered and are persuasive in view of their cancellation.

16. Applicant's arguments filed 14 May 2007 with respect to the rejection of claims 2-3, 9, 22-25, 27 and 30 35 U.S.C. 112, second paragraph, have been fully considered and are persuasive. The rejection of claims 2-3, 9, 22-25, 27 and 30 has been withdrawn.

17. Applicant's arguments filed 14 May 2007 with respect to the rejection of claims 1-7, 9-11, 15-16, 18-20 and 22-28 under 35 U.S.C. 102(b) citing Kroll ('955) have been

fully considered and are not persuasive. Applicant contends that Kroll does not teach piezoelectric elements which expand and contract, in accordance with claim 1.

However, this argument is not persuasive. Kroll indeed teaches a single element transducer **100A** ("piezoelectric element") which expands longitudinally in response to a received electric signal, while single element transducer **100B** ("piezoelectric element") responds by contracting longitudinally (col. 8, lines 53-56). In view of the foregoing, the rejection under 35 U.S.C. 102(b) citing Kroll ('955) has been maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

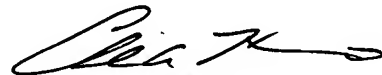
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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Art Unit 3735


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